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Attorney Docket No: 675000-353

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	**Lori Ann Wilson, et al.**	: **Group:**	**1761**
Serial No.	:	**09/751,397**	: **Examiner:**	**Thuy Tran Lien**
Filed	:	**01/02/2001**	: **Confirmation No.**	**7520**
Title	:	**WAXY WHEAT PRODUCTS AND PROCESSES FOR PRODUCING SAME**		

REPLY BRIEF

Mail Stop Appeal Reply Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

This reply brief is being submitted in response to the Examiner's Answer mailed on April 28, 2006.

I. Status of claims

Claims 1-3, 6 and 8-51 remain in the application, claims 4, 5 and 7 have been cancelled. Claims 13-33 and 36-51 have been withdrawn from consideration. Claims 1-3, 6, 8-12, 34 and 35 have been finally rejected and are the subject of this appeal.

II. Grounds of rejection to be reviewed in this reply brief

The ground of rejection on review addressed in this reply brief is whether claims 1-3, 6, and 8-12 are properly rejected under 35 U.S.C. §103(a) as being unpatentable over Alderman US Pat No. 2,526,792 in view of Nakamura et al. "reduction of waxy amylose free wheats" and the book "Wheat Chemistry and Technology". Claims 34 and 35 were addressed in the Appeal Brief and will not be readdressed here.

III. Argument

A. Rejection of claims 1-3, 6, and 8-12 under 35 U.S.C. § 103(a) based on Alderman (US 2,526,792) in view of Nakamura et al. and the book "Wheat Chemistry and Technology".

The Examiner rejected claims 1-3, 6 and 8-12 under 35 U.S.C. §103(a) based on Alderman in view of Nakamura et al. and the book "Wheat Chemistry and Technology". The Examiner relies on Alderman as disclosing a cooked-puffed waxy cereal food formed into ready-to-eat cereal foods of the breakfast type. The Examiner admits that Alderman does not disclose waxy wheat or coating the grain with an edible coating. The Examiner relies on Nakamura et al. as disclosing the production of waxy wheat grains. The Examiner relies on the book as disclosing the protein contents of soft and hard wheats. Utilizing the disclosure of Nakamura et al. the Examiner states it would be obvious to use waxy wheat disclosed in Nakamura et al. to produce the waxy cooked cereal grains disclosed by Alderman. The Examiner assumes that when the waxy wheat of Nakamura et al. is used it would be obvious that the grains would have the claimed allele and amylose content of the present application. The Examiner furthermore states that the book discloses that the common range of protein is from 9-15% and thus states it would be obvious to utilize a waxy wheat having that protein level. Still referring to the Alderman disclosure the Examiner states "Since the cereal product is puffed and it is a ready-to-eat cereal, the product is buoyant because cereal floats in liquid. The Alderman product is dried; it is made of cereal grain and it is the same type of product as claimed. Thus, it is obvious the product has the same storage stability as claimed."

Rejection of a claim under 35 U.S.C. §103 requires that the Examiner point to some teaching, suggestion, or motivation found within the references themselves that would lead one

of ordinary skill in the art to combine the references and having combined the references to make the claimed invention obvious in light of a teaching, suggestion or motivation found within the references themselves. Absent the Examiner's ability to point to such a specific teaching, suggestion, or motivation the rejection of the claims under 35 U.S.C. §103 based on a combination of references is improper and must be withdrawn.

Claim 1 is in independent form and claims a "cooked, buoyant whole grain waxy wheat comprising no more than about 10% amylose starch, and less than 20% by weight protein characterized by being gelatinized throughout and storage stable in the absence of additives that inhibit development of rancidity for at least six months."

The product disclosed in Alderman is not similar to the claimed product and the process utilized by Alderman does not produce the product as claimed in claim 1 of the present application. Specifically, the Alderman process does not result in a "cooked, buoyant whole grain waxy wheat comprising no more than about 10% amylose starch, and less than 20% by weight protein characterized by being gelatinized throughout and storage stable in the absence of additives that inhibit development of rancidity for at least six months."

Accompanying the previously submitted Appeal Brief is a declaration under 37 C.F.R. §1.132 that includes submission of supporting data. The declaration is signed by and the data was generated under the direction of Lori Wilson, one of the inventors of the present invention. The declaration presents evidence directly comparing a waxy wheat that is processed according to Alderman's process versus one processed according to the present application. The declaration provides data that clearly demonstrates that even when beginning with two samples from the same waxy wheat stock the two processes produce entirely different products and that the product claimed in the present application is different and certainly not obvious in view of

the product and processes disclosed in Alderman and the other cited references. The data specifically disclose that waxy wheat taken through the process of Alderman does not result in a whole grain compared to the present process, does not result in complete gelatinization compared to the present process, and that the product produced is not storage stable in the absence of additives that inhibit the development of rancidity compared to the present process.

The declarant has over twenty-five years of experience in the area of research and development in quality control in cereals and cereal processing at the Kellogg Company. The declarant has a BS in food science and human nutrition from Michigan State University. To demonstrate that the whole grain waxy wheat of the present invention is different from and not obvious based on the disclosures of Alderman, Nakamura et al. and the book the declarant took two portions of a whole grain waxy wheat from the same grain lot and origin. One portion was treated per example 5 of Alderman, which is the only example wherein he uses a whole grain in his process, and the other portion was treated as per the present application. As noted in the declaration and as is known by one of ordinary skill in the art in the industry "whole grain" as utilized in the present claims is defined as intact kernels of grain or fractions thereof that contain all three parts of the whole grain, namely the outer bran, the endosperm, and the germ in tact. When portions of these three parts are removed from the grain during processing it ceases to be whole grain.

As is noted in paragraph 6 of the declaration to test the Alderman process 15 pounds of the whole grain waxy wheat were combined with 1.31 pounds of sugar, 0.44 pounds of salt, and 5 pounds of water. The mixture was cooked at 15 pounds per square inch of steam for one hour and forty minutes in a rotary cooker at 2.3 rpms. The cooked waxy wheat was then dried at 250°F for approximately 40-50 minutes to a final moisture of 16.1%. The cooked waxy wheat

was then tempered per the Alderman procedure for 24 hours. The cooked and tempered waxy wheat was then run through flaking rollers. Finally, the milled, cooked waxy wheat was toasted per example 5 of Alderman. The resulting product was then tested for a variety of parameters related to claim 1 including measures of whether it was still a whole grain, the degree of gelatinization, and storage stability.

The other portion of whole grain waxy wheat was treated as described in paragraph 7 of the declaration in accordance with the present application. In a first step 23 pounds of the whole grain waxy wheat were placed in a rotary cooker and steamed at 15 pounds per square inch for 15 minutes at 2.3 rpms. As described in the present application, the steaming process used in the present specification inactivates the lipases which are believed to make cooked whole grain waxy wheat unstable and subject to rancidity. Inactivation of lipases requires more than just heating the grain to a certain temperature it is the way in which it is heated, the time of heating and the post heating steps. The steamed whole grain waxy wheat was then bumped by passing it through rollers set at 300 mm. The bumping of the uncooked waxy wheat causes small fissures in the bran layer but does not remove any of the bran layer. Then 15 pounds of the bumped waxy wheat was mixed with a slurry of 1.31 pounds of sugar, 0.44 pounds of salt, and 3.0 pounds of water. The fissures allow the slurry to penetrate the whole grain during the cooking process. The mixture was cooked in a rotary cooker at 15 pounds per square inch, 2.3 rpms for 45 minutes. During this cooking process the whole grain waxy wheat will tend to become like glue and holds the outer bran layer onto the whole grain and maintains the wholeness of the grain. The cooked whole grain waxy wheat was then dried at 250°F for approximately 20 minutes to a final moisture of 16.4%. Next the warm, dried whole grain waxy wheat was roller milled while at a temperature of from 100 - 120°F and then cooled and tempered for 24 hours.

Roller milling the cooked whole grain waxy wheat while it is warm ensures that the starches are at a temperature above their glass transition state so that they are pliable and can be formed without shattering, which would cause loss of portions of the outer bran making the grain a non-whole grain. Finally, the tempered whole grain waxy wheat was toasted as noted for Alderman. The resulting product was then tested for a variety of parameters related to claim 1, including measures of whether it was still a whole grain, the degree of gelatinization, and storage stability.

One of the key limitations in claim 1 of the present invention is that the wheat be "a whole grain waxy wheat". As noted above, whole grain has a very specific definition in the industry and is known to those of ordinary skill in the art to require that all three portions of the wheat kernel be present, namely, the outer bran, the endosperm, and the germ and intact. Unlike the Examiner's suggestion in the Answer there are not "degrees of wholeness" the grain is either whole grain or it is not. Being whole grain requires that all three portions of the grain be present and intact. Once portions of the layers are lost the grain ceases to be whole grain and it becomes a processed grain. Obviously there are degrees of processing ranging from partial removal of the outer bran layer to complete removal of the outer bran layer. Additional processing steps can even remove portions of the endosperm. The degree of processing is determined by the end use of the product and desired characteristics of the product. Soluble and insoluble fiber of waxy grains are found in the outer bran layer of the grain, thus measuring the levels of insoluble and total fiber in a grain product can be used to determine whether a grain is a whole grain or not. A reduction in soluble or total fiber indicates that part of the outer bran layer has been lost and thus the product is not a whole grain. Methods for determining soluble and total fiber are common in the industry, well known to those of ordinary skill in the art, and the methods are so well known that the exact process used was not presented in the declaration. As noted in the declaration Lori

Wilson has 25 years of experience in the food industry specifically in cereals and cereal processing. Kellogg is a multinational cereal company that deals with millions of pounds of cereal grains per year and is well able to reliably measure the level of soluble and total fiber in any grain sample. Because both wheats used in the tests discussed in the declaration were taken from the same source and lot they should produce the same level of insoluble and total fiber provided that they both represent whole grain waxy wheat.

Applicants admit that Alderman discloses starting with a whole grain waxy grain. Claim 1, however, is directed to and claims a whole grain waxy wheat product and Alderman does not disclose a process for producing such a product. As the declaration states the product produced according to the method of Alderman had an insoluble fiber level of 6.29 weight percent and a total fiber level of 9.99 weight percent. By way of contrast, the product produced according to the present invention and as claimed in claim 1 had an insoluble fiber level of 10.14 weight percent and a total fiber level of 13.56 weight percent. This data is presented in paragraph 8 of the declaration. Thus, the product prepared according to the present invention had an insoluble fiber level that was 161% of the value found in the grain processed according to Alderman and a total fiber level that was 135% of the total fiber found within the grain processed according to Alderman. Thus, the Alderman product has significantly less soluble and total fiber compared to the product of the present invention indicating that the Alderman product has lost portions of the outer bran layer which contains the fiber. The Alderman product still has some outer bran layer, but it is not a whole grain anymore as required by claim 1. The product processed per the Alderman process has 37.96% less soluble fiber and 26.32% less total fiber than the product processed according to the present invention. The fact that the Alderman product still has some soluble and total fiber does not mean it is whole grain as suggested by the Examiner, even highly

processed and refined flour has some fiber, but no one of ordinary skill in the art would suggest that it is therefore whole grain as required by claim 1. The loss of soluble and total fiber in the Alderman product indicates a loss of part of the outer bran layer and thus it is no longer whole grain as required by claim 1.

Claim 1 further requires that the whole grain waxy wheat be gelatinized throughout. As known to those of ordinary skill in the art the degree of gelatinization can be measured in a number of ways including by measuring water solubility, alkali solubility, and by rapid viscosity analysis. As known to those of ordinary skill in the art the higher the percentage of water solubility or alkali solubility the greater the degree of gelatinization. The water solubility is measured in terms of grams per 100 grams in water. The Alderman product had a value of 18% while the product prepared according to the present invention had a value of 23%. The alkali solubility of the Alderman product was 50% while the product of the present invention had a value of 66%. The viscosity measurements were taken over time as the temperature of the solution is varied and can be seen in the attached figure of the declaration throughout the entire range of time and temperature the Alderman product had a much higher viscosity which is a clear indication that it is less gelatinized than the product as claimed in claim 1 of the present invention. The higher degree of water solubility and alkali solubility of the product prepared according to the present invention also indicates that the product was more thoroughly gelatinized than that of Alderman. These measures for gelatinization are described and discussed in paragraphs 9 of the declaration. Those of ordinary skill in the art know how these measurements are performed and that they are commonly used to evaluate gelatinization of grains. The Examiner assumes that since the Alderman process has a longer cooking period it must result in greater gelatinization, this seems intuitive. The data, however, shows that the

Alderman product is less gelatinized than the product produced according to the present invention. The present process results in greater gelatinization using a shorter cooking time because of the other processing steps. By three measures the Alderman product is not fully gelatinized as is the product of the present invention.

Finally, claim 1 requires that the product be stable in the absence of additives that inhibit rancidity for at least six months. The data in the specification shows that this is easily achievable with the product of the present invention and in fact stability beyond twelve months is also easy to achieve. The stability of the Alderman product and the product prepared according to the present invention were tested using two stability protocols and by measuring the head space hexanal. Use of head space hexanal to determine stability is described in the specification page 10, lines 4-13, page 17, lines 15-25, and page 21, line 30 through page 23. Measurement of hexanal levels in headspace is commonly used in the industry to detect rancidity in cereal products. The hexanal levels in the headspace were measured after storage from four months at 70°F and 35% relative humidity which represents ambient storage conditions for cereal products for four months. In a second protocol some of the samples were moved to conditions of 100°F and 70° relative humidity for either two or eight additional weeks after the four month storage period. Storage under these high temperature and humidity conditions is used in the industry to simulate longer term storage at ambient conditions in an accelerated fashion. The results were presented in paragraph 10 of the declaration. The results dramatically showed that the headspace hexanal level in the Alderman product was higher at all points and conditions measured compared to the product prepared in accordance with the present invention. In fact, after the first two weeks of accelerated conditions the Alderman product had a hexanal headspace level that was 3.58 ppm which was 358% of that measured at four months. The product prepared

according to the present invention only had an increase to 1.28 ppm which was 193% of the four month measure and was significantly lower than that found in the Alderman product. By the end of eight weeks of accelerated conditions the Alderman product had a hexanal headspace level of 6.98 ppm which is 698% of the four month measure and was clearly rancid. In the industry headspace hexanal levels greater than 5 ppm are considered to represent clear rancidity. By way of contrast, the present invention product was still well below the Alderman product at 3.49 ppm and well below the rancidity threshold.

The Examiner claims there is no showing of storage stability for 6 months in the declaration and thus the declaration is not commensurate with the scope of the claim. This is clearly shown in the declaration as the accelerated 2 and 8 week tests followed the 4 month test and even after all of this the samples of the present invention were still not rancid while those of Alderman clearly were as determined by hexanal head space measurements. True the hexanal head space is not claimed as the Examiner states, however, stability for 6 months is and the hexanal head space measurements show that the Alderman product is not stable by these recognized measurements and the present invention is stable.

In summary, the declaration shows by a number of different measures that the product of the present invention is clearly different from and not obvious in view of the disclosure of Alderman, Nakamura et al. and the book. Furthermore, the results clearly demonstrate that even if it were obvious to substitute waxy wheat of Nakamura et al. in the Alderman process following that process would not produce a product as claimed in claim 1 of the present invention. This is so because that is precisely what was tested in the declaration, namely taking a waxy whole wheat grain and following the Alderman process and comparing that to a whole grain sample prepared according to the present invention. The Examiner states that there is not

sufficient data from which one could conclude that this is the case because the experiments were only performed once. While it may be true that in an isolated measure a single repetition could be insufficient here we have a situation where numerous parameters were measured all of which clearly demonstrate that three of the key limitations found in claim 1 are not present in a product produced according to the Alderman process. Therefore, the rejection of claim 1 and the claims which depend therefrom under 35 U.S.C. §103 based on Alderman, Nakamura et al. and the book is improper and should be withdrawn.

Respectfully submitted,

DICKINSON WRIGHT, PLLC

June 28, 2006
Date

Randy Shoemaker, Reg. No. 43,118
Dickinson Wright, PLLC
38525 Woodward Avenue, Suite 2000
Bloomfield Hills, MI 48304-2970
(248) 433-7383

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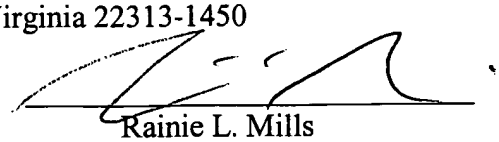

Rainie L. Mills